In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one must engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that are arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process—which "is focused on *equivalence*, not safety" (*id.* at 493 (emphasis in original) (internal quotation omitted)) and which does "not 'require'" a medical device "to take any particular form for any particular reason" (*ibid.*)—did not preempt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device and thus plaintiffs would not have been injured. The Court—noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (531 U.S. at 353)—found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to

the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 351.

B. The Extensive Regulatory History Of The Model 4004 And 4004M Devices.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 531 U.S. at 344; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. The path to approval of the Models 4004 and 4004M pacemaker leads at issue in this case demonstrates the thoroughness of that review.[1] When the FDA approved Medtronic's application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of a predecessor device, the Model 4003 lead. Before the FDA determined, in approving the Model 4004M and 4004 PMAs, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that those leads were safe and effective for their intended use, the devices and their direct predecessor models (in particular, the Model 4003) had been rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

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[1] As explained further below (at 9–10), the Model 4004 was the immediate predecessor to the Model 4004M; the only difference between the two is a minor change to a connector pin. Both devices were subjected to similar agency review—the successor 4004M lead was approved through a "PMA supplement" to the 4004 lead approval. See page 10, *infra*; see also Pet. 11 n.3.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004 and Model 4004M pacemaker leads.[2]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.
- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.
- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.
- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request and required it to continue the investigation under the existing limits.
- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.
- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983, required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing and (2) "the fate of the implanted lead, in terms of po-

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[2] This description is based on the affidavit of Charles H. Swanson, which is contained (at J.A. 98-119) in the Sixth Circuit's Joint Appendix in *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001), a case with which this case was consolidated for purposes of discovery. See Pet. App. 13a; see also *Kemp*, 231 F.3d at 219 (summarizing PMA history of Model 4004 and 4004M leads).

tential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.
- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who had particular experience recognizing potential complications from the leads.
- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.
- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.
- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.
- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.
- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.

- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition, Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.
- In April 1986—30 months after Medtronic first filed a PMA request—the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.
- On May 23, 1986, the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that the device was safe and effective for its intended use and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.
- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.
- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.
- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had been done only on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.
- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was

made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA Supplement for the Model 4004M lead on March 28, 1990, subject to the same conditions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004 and 4004M leads lasted *eight years*—from March 1982 to March 1990—and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M lead, the Model 4004 lead, and the predecessor models to these leads.

C. Petitioners' Cases In The Lower Courts.

1. Petitioners are individuals, or immediate relatives of individuals, who were implanted with pacemakers employing the Model 4004 and 4004M leads. Petitioners filed four separate lawsuits against Medtronic in the Southern District of Ohio, consolidated for all purposes on January 18, 2002, asserting that they were injured after the implanted leads purportedly malfunctioned.

In their initial complaints, the earliest version of which was filed on January 24, 1997, petitioners asserted 11 state common law causes of action, including claims for strict liability, negligence, negligence per se, negligent and fraudulent misrepresentation, failure to warn, breach of implied and

express warranties, and negligent and intentional infliction of emotional distress.[3]

2. Petitioners' cases were consolidated for purposes of discovery with *Kemp* v. *Medtronic, Inc.*, No. C-1-97-103 (S.D. Ohio), which presented basically identical factual assertions and legal claims.

The district court in *Kemp* granted summary judgment to Medtronic on all counts. See Pet. App. 9a-11a. In the first of two summary judgment decisions, the court held as a threshold matter that the PMA process establishes specific federal requirements that preempt common law claims that would have the effect of creating state requirements different from or in addition to those federal requirements. See *id.* at 10a. The court then found that the plaintiffs' design, warning, and warranty claims were preempted inasmuch as recovery would in fact impose state requirements different from or in addition to the federal requirements. See *ibid.* The court also granted summary judgment on plaintiffs' manufacturing defect claim on the basis of preemption, insofar as that claim alleged negligence despite adherence to the FDA-imposed requirements.[4] See *ibid.* The court did, however, grant plain-

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[3] The first suit to be filed was *Cupek* v. *Medtronic, Inc.*, No. C-1-97-105. *Padgett* v. *Medtronic, Inc.*, No. C-1-97-413, *Bocock* v. *Medtronic, Inc.*, No. C-1-98-148, and *Shindelman* v. *Medtronic, Inc.*, No. C-1-98-178, were filed subsequently. The complaints in *Cupek*, *Bocock*, and *Shindelman* were essentially identical; the *Padgett* complaint contained only a subset of the claims asserted in the other three cases. The cases were ultimately consolidated under *Cupek*. See docket entry 42 at J.A. 9, in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). For ease of exposition, we will refer to the complaint in *Cupek*—which upon consolidation became the sole operative complaint—as petitioners' initial complaint. The case below was named for Ethel Cupek, the first named plaintiff in the first filed case, but she was voluntarily dismissed from the case in September 1998. See Pet. 14 n.4.

[4] The district court also granted Medtronic summary judgment on the plaintiffs' allegation of fraud on the FDA, holding that claim to be preempted as well. See Pet. App. 10a. See also *Kemp*, 231 F.3d at 216 & 233 n.14 (noting that plaintiffs' fraudulent misrepresentation claim—identical

tiffs leave to file an amended complaint alleging negligent deviation from the FDA-imposed manufacturing requirements, a claim that the court found would not be preempted. After a corresponding amended complaint was filed, the court issued a second summary judgment decision in favor of Medtronic, finding as a factual matter that Medtronic had not deviated from the federal requirements in manufacturing the 4004M lead. See *id.* at 11a.

The *Kemp* plaintiffs appealed to the Sixth Circuit. (The district court administratively closed these four consolidated cases while the Sixth Circuit considered the plaintiffs' appeal in *Kemp*. See Pet. App. 9a.) The Sixth Circuit affirmed the district court's judgment in all respects. See *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); Pet. App. 12a. Expressly agreeing with the Seventh Circuit, the court of appeals found that "'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'" 231 F.3d at 226–27 (quoting *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997)). The court of appeals further found that "a jury verdict in plaintiffs' favor * * * would amount to a state requirement 'different from, or in addition to,' the federal requirements." *Id.* at 232. Accordingly, the court held that plaintiffs' claims were "preempted by § 360k of the MDA." *Id.* at 237. The *Kemp* plaintiffs petitioned for certiorari, which this Court denied. See 534 U.S. 818 (2001).

3. Following the denial of certiorari in *Kemp*, petitioners in this case simultaneously moved to reinstate their case and for leave to file an amended complaint.

Petitioners' proposed amended complaint contained eight state law counts. Counts I and II alleged negligence and/or strict liability for failure to warn and failure to recall after

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to that asserted by petitioners here—was characterized by plaintiffs as, and necessarily based upon, an allegation of fraud on the FDA).

PMA approval had been received. Count III alleged negligence per se for failure to comply with federal requirements consistent with state requirements. Count IV alleged negligence per se for failure to comply with the conditions of approval. Counts V–VIII alleged strict liability, negligence, and breach of warranty in connection with the leads' design, manufacture and use. See Pet. App. 14a–15a.

The district court granted the unopposed motion to reinstate but denied petitioners leave to amend with respect to all counts but their proposed Count III. According to the court, the amendment was futile as to the remaining counts because those claims would all be preempted by federal law. See Pet. App. 18a–24a. The court instructed petitioners to file a new amended complaint limited only to their Count III (see *id.* at 23a–24a), but petitioners failed to do so (see *id.* at 27a).

Thereafter, the district court—relying on the Sixth Circuit's decision in *Kemp* and this Court's decision in *Buckman*—granted Medtronic summary judgment on petitioners' initial complaint. See Pet. App. 30a–31a.[5]

4. Petitioners appealed the district court's denial of leave to amend their complaint. See Pet. App. 4a.[6] The Sixth Circuit affirmed in all respects.

With respect to proposed Counts I and II, which alleged a failure to warn and a failure to recall after PMA approval had been received, the court of appeals noted that "the FDA requires continuous updates as part of the [PMA] process" and that "[t]hese updating requirements specifically address warnings and recalls associated with medical devices." Pet.

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[5] With respect to petitioners' claim of negligence per se, the district court found that, as a matter of fact, petitioners had failed to proffer any evidence to support the assertion that Medtronic had deviated from the FDA's manufacturing requirements. See Pet. App. 31a.

[6] Petitioners did not continue to press the assertions raised in their proposed Count III. See Pet. App. 4a.

App. 5a (citing 21 U.S.C. §§ 360h(a), 360(e)(1), 360h(e)(2)(a); 21 C.F.R. §§ 803.50, 810.10). Consequently, the court held, "[a]ny claim, under state law * * * that [Medtronic] failed to warn patients beyond warnings required by the FDA, or that [Medtronic] failed to recall a product without first going through the PMA supplement process would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." *Id.* at 6a.[7] Accordingly, the court concluded, proposed Counts I and II were preempted under the MDA.

The court of appeals also affirmed the refusal to grant leave to amend as to proposed Count IV. The court explained that this claim was "a disguised fraud on the FDA claim" (*id.* at 5a) and that granting leave to amend would have been futile because this Court, in *Buckman*, had held that "federal law preempted such claims." *Ibid.*

Petitioners conceded that under *Kemp* their remaining proposed counts (Counts V–VIII), were preempted by federal law, but raised the denial of leave to amend as to these counts for purposes of issue preservation. See Pet. App. 7a, 15a; see also J.A. 120 in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). The court of appeals—having already carefully analyzed and applied *Lohr* to identical claims in *Kemp* (see 231 F.3d at 223–25)—declined to revisit its prior decision, thus reaffirming its holding that state law claims for strict liability, negligence, and breach of warranty in connection with the design, manufacture, and marketing of a PMA-approved device are preempted by federal law. Pet. App. 7a.

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[7] The court of appeals also noted that petitioners' "proposed amended claims undermine [petitioners'] preemption arguments, because those claims assert that [Medtronic] has duties 'independent of any obligations . . . to comply with applicable federal regulations." Pet. App. 6a (omission in original); see also J.A. 114–15, in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005).

REASONS FOR DENYING THE PETITION

Petitioners assert (Pet. at 1–2, 15–20) that review is necessary in this case because of the purported disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the petition, as it denied the virtually identical petitions filed in *Kemp* and *Martin*. As we explain in Part I.A, the lower courts are in significantly less disarray than petitioners suggest. Moreover, in light of the *amicus* brief recently filed by the United States in *Horn*—as well as this Court's decisions in *Buckman* and *Geier*—any lingering disagreement within the lower courts is now likely to disappear. See Part I.B, *infra*. In any event, given the extensive FDA scrutiny of the Model 4004 and Model 4004M pacemaker leads, the Sixth Circuit's decision is plainly correct. See Part II, *infra*.

I. THERE IS NO REASON FOR THIS COURT TO REVISIT ITS RULING IN *MEDTRONIC, INC.* V. *LOHR*.

A. Any Disagreements Among The Lower Courts Are Minimal And Diminishing.

Petitioners assert that the lower courts are "deeply divided" on the question whether the FDA's approval of a medical device through the PMA process preempts inconsistent state-law damages claims arising from the design, manufacture, and labeling of such devices. Pet. 15–16. Indeed, petitioners assert that there are conflicts as to both whether the PMA process imposes specific federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. In fact, although a few courts, in outdated opinions, have misinterpreted *Lohr* on each of these issues, the great weight of authority—including *all* recent authority—favors the Sixth Circuit's position on each question.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to a device are preemptive under the MDA. See 518 U.S. at 500-501.[8] Based on this Court's discussion of the "rigorous" nature of the PMA process, and the Court's comparison between the 510(k) process (which "reflect[s] important but entirely generic concerns," *Lohr*, 518 U.S. at 501) and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements," *ibid.*), the vast majority of courts have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 5a; *McMullen* v. *Medtronic, Inc.*, No. 04-3678, 2005 WL 2043827 (7th Cir. Aug. 26, 2005); *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 171–73 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226-27; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v.

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[8] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 24–26, *infra*.

Allergan Med. Optics, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to the decisions of the Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of the Pennsylvania, Rhode Island, and Texas Supreme Courts, petitioners can identify (at Pet. 17) decisions of only one federal court of appeals and one state supreme court, *cf.* S. Ct. R. 10, that did not find PMA approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while at odds with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found that the PMA process "is clearly specific to the device under review" and that the FDA's Conditions of Approval "constitute specific federal requirements," 167 F.3d at 1376, yet then somehow concluded that the requirements were not "applicable under [the MDA] to the device,'" *ibid.* (quoting 21 U.S.C. § 360k(a)(1)), and did not establish "a specific requirement that applies to a particular device," *id.* at 1377. The decision is not only internally inconsistent and factually incorrect, but also contrary to *Lohr*. The *Goodlin* court denied preemptive effect to the concededly specific federal requirements, apparently because the FDA's Conditions of Approval were "not promulgated with respect to [a] 'particular device.'" *Ibid.* Yet, so long as the specific federal requirement is applicable to a given device, *Lohr* does not demand that the requirement be applicable *exclusively* to that device. In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that no aspect of the PMA process is specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: First, the court

held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*)—a statement that is untrue both in general (see 21 C.F.R. § 814.80 (prohibiting the manufacturer from making any change without FDA authorization to a device that has been approved by the agency through the PMA process if such change would affect the device's safety or effectiveness)), and in this case, where the FDA repeatedly required modifications of the product and its labeling (see pages 5–10, *supra*). Second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, see 531 U.S. at 343, this decision is plainly incorrect.[9]

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[9] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 17 n.6), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite in footnote 6 are IDE rather than PMA cases and both specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996) (en banc); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), whereas the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

2. On the state side of the *Lohr* preemption equation, petitioners assert (at 18) that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[10] a decision that is plainly correct under *Lohr* (see pages 26–28, *infra*). Only one federal court of appeals or state court of last resort, *cf.* S. Ct. R. 10, has relied on a contrary finding to limit the preemptive scope of the MDA—the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997).[11] *Oja* is one of the earliest appellate decisions to in-

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[10] See, *e.g.*, Pet. App. 6a; *McMullen*, 2005 WL 2043827, at *4; *Horn*, 376 F.3d at 173–177; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 213 F.3d at 224; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[11] Neither *Niehoff* nor *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004), the only state supreme court decisions cited by petitioners, holds that state common law claims are not subject to preemption when a medical device has received FDA approval through the PMA process. Petitioners' parenthetical assertion that the Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822 ("[t]he claim * * * of preemption to the defective design allegation fails because there is no specific federal requirement"). As discussed above (at page 18 n.10), the *Niehoff* court also focused on the significant differences between the PMA process and the IDE process. In *New Womyn*, a case brought by the state attorney general under the state's consumer fraud statute, the device at issue had not been approved by the FDA at all, let alone after "running the gauntlet of the PMA process." *Lohr*, 518 U.S. at 494. Indeed, an FDA "employee with extensive experience in the review of applications regarding new medical devices" testified that a device similar to that at issue in *New Womyn* "was on display in the public lobby of the FDA building in a collection of what the FDA labeled 'quack devices.'" *New Womyn*, 679 N.W.2d at 597. Thus, even if the Supreme Court of Iowa had discussed whether a state law damages claim could in theory be preempted (which it did not), there was no specific federal requirement in *New Womyn* to preempt any state law claim.

terpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state common law duty would "have the effect of establishing a substantive requirement of a specific device"—even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See page 27, *infra*.[12]

This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In the eight years since *Oja*, there has been no movement by any other court toward that court's erroneous analysis. Moreover, given this Court's holding in *Bates* v. *Dow Agrosciences LLC*, 125 S. Ct. 1788, 1798 (2005), that the term "requirements" in the identically-worded FIFRA includes common law claims, the unanimous view of the other courts of appeals that such claims may be preempted, and the United States' similar view as expressed in its *amicus* brief in *Horn* (see pages 21–23, *infra*), there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*.

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[12] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements—despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

B. The Lower Courts Should Be Allowed To Consider The Implications Of The FDA's *Amicus* Brief In *Horn*.

In *Lohr*, this Court recognized that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495–496. The Court further recognized that, as the federal agency to which Congress has delegated the authority to implement the MDA, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted." *Id.* at 496 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Given "the ambiguity in the statute" and "the congressional grant of authority to the agency on the matter contained within it," the Court found it appropriate to "giv[e] substantial weight to the agency's view of the statute." *Ibid.*

The FDA has recently provided authoritative guidance on the scope of § 360k's preemptive effect in the PMA context. At the request of the Third Circuit, the United States submitted an *amicus* brief on behalf of the FDA in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004). The FDA's *amicus* brief explains at length and in detail why "FDA pre-market approval for a new medical device preempts state law tort judgments." Brief for United States as *Amicus Curiae*, 2004 WL 1143720, at *2.

With respect to the federal side of the equation, the FDA stated unequivocally that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device.'" *Id.* at *16. The FDA noted that "[a]lthough the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and

market the product in compliance with the specifications as approved by [the] FDA." *Id.* at *24.

With respect to the state side of the preemption equation, the FDA endorsed the view—subscribed to by a majority of the Justices in *Lohr*—that "state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action 'would impose a requirement different from, or in addition to, that applicable under the FDCA.'" *Id.* at *18 (quoting *Lohr*, 518 U.S. at 511 (O'Connor, J., concurring in part and dissenting in part)). The FDA observed that, absent an allegation that the device in question deviated from the requirements imposed by the FDA through the PMA process, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Ibid.*

The FDA also emphasized in its brief the "very strong public policy considerations" that support finding PMA approval preemptive of state common law claims. *Id.* at *25. According to the FDA—the agency charged with implementing the MDA—"[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices." *Ibid.* As the agency explained, during the PMA process it conducts "a thorough review of a substantial scientific record" (*id.* at *16) and performs a "careful balancing" of the benefits and risks associated with a particular device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law" (*id.* at *31).

Given the agency's "unique role in determining the scope of § 360k's pre-emptive effect" (*Lohr*, 518 U.S. at 495–496),

the FDA's clear guidance in *Horn* further demonstrates that there is no need for this Court to grant review in this case. The FDA's "reasoned analysis" (U.S. Br., 2004 WL 1143720, at *30) is entitled to substantial weight as "the agency's fair and considered judgment on the matter in question." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties). This is especially true when coupled with this Court's renewed recognition of "the PMA review's rigor" (*Buckman*, 531 U.S. at 348), and Justice Stevens' reminder that "in *Medtronic, Inc.* v. *Lohr*, [this Court] recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties" (*Geier*, 529 U.S. at 897 (Stevens, J., dissenting)).

There is simply no reason to believe that those few courts that misinterpreted *Lohr* soon after it was decided will not now take heed of the FDA's *amicus* brief in *Horn* and join the clear consensus finding state common law claims that would impose requirements that are "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of a device to be preempted by federal law. In the unlikely event that those courts, upon reconsideration, choose to adhere to their prior decisions, the Court can grant review at that time.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, with the views of the FDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device

or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur, there must be a federal requirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Sixth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific). Moreover, the decision below is entirely consistent with the views of the FDA, which has declared that the PMA process "establishes 'specific requirements' applicable to a 'particular device.'" *Amicus* Brief in *Horn*, 2004 WL 1143720, at *16.[13]

It is especially clear that in *this* case the PMA process established specific requirements applicable in particular to the Model 4004 and 4004M leads. We described above (at pages

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[13] The FDA's view is well supported by statute. Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

5–10) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plans to distribute the 4004 and 4004M leads. During that process, "[t]he design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process." *Martin*, 254 F.3d at 584–85; see also *Kemp*, 231 F.3d at 226-27 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913).

Significantly, approval through the PMA process entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)); see also *Amicus* Brief in *Horn*, 2004 WL 1143720, at *16 ("The approval perforce embodies the agency's conclusion that there is a 'reasonable assurance of safety and effectiveness' of the device."). The determination that a product is safe and effective, made after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" (21 U.S.C. § 360c(a)(2)(C))—in a process characterized by this Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 531 U.S. at 349)—is of necessity the determination that the attributes of that device are an appropriate compromise that should not be modified by state law. See *Amicus* Brief in *Horn*, 2004 WL 1143720, at *29 ("state co-regulation" through tort actions "may disrupt the careful balancing performed by [the] FDA in the PMA process").

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), *cf.* Pet. 22, but—as evidenced by the FDA's *amicus* brief in *Horn*—that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted

when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully be marketed without application for premarket approval. * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue by expressly exempting it (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary if the PMA process did not establish requirements otherwise preemptive of the state law.

2. The Sixth Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device should have been manufactured, designed or labeled in a manner different from that required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes pre-

empt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part).[14] Where a state law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Indeed, as noted by the FDA, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Amicus* Brief in *Horn*, 2004 WL 1143720, at *18.

Here, the PMA process imposed specific requirements on Medtronic, including the requirement to make its Model 4004 and Model 4004M leads using the specific design approved, which encompassed using a particular material for the leads' insulation and using the manufacturing processes Medtronic described in its PMA application. The district court found that petitioners had proffered no evidence suggesting that Medtronic had deviated from the requirements imposed by the FDA through the PMA process. Pet. App. 31a. Thus, were a jury to impose liability on Medtronic under

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[14] Significantly, Justice Stevens, who wrote the plurality opinion in *Lohr*, has himself stated that *Lohr* "recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties." *Geier*, 529 U.S. at 897 (Stevens, J., dissenting). See also *Geier*, 529 U.S. at 867 (noting that "a majority of this Court" in *Lohr* recognized that state tort actions may be preempted as imposing conflicting "requirements"); *Bates*, 125 S. Ct. at 1798.

state law, that jury would of necessity be imposing a requirement "different from" or "in addition to" that imposed by the FDA under federal law.[15]

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.

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In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of the FDA's *amicus* brief in *Horn* and through further litigation in the lower courts. Petitioners provide no good reason why the Court, having repeatedly de-

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[15] As the Sixth Circuit noted below, petitioners' proposed amended Counts I and II assert that under state law Medtronic "has duties 'independent of any obligations . . . to comply with applicable federal regulations.'" Pet. App. 6a. The court of appeals correctly observed that "[s]uch independent duties are, at the very least, 'in addition to' federal requirements, and may very well be 'different from' federal requirements." *Ibid.*

clined to review this issue, should grant review here, or why the issue deserves the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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